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K&L GATES LLP 535 SMITHFIELD STREET PITTSBURGH, PA 15222			EXAMINER TURK, NEIL N	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/042,904	Applicant(s) LIN ET AL.	
	Examiner NEIL TURK	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 5th, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 12-40 is/are pending in the application.
- 4a) Of the above claim(s) 27-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 12-26 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/13/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on May 5th, 2008. Claims 10, 12-23, and 25-40 are pending. Claims 11 and 24 have been cancelled. Claims 27-40 are newly added. Claims 27-40 have been withdrawn from consideration as being drawn to non-elected inventions.

Election/Restrictions

Newly submitted claims 27-40 directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Newly added independent claims 27, 30, 35, and 40 are drawn to patentably distinct subcombinations of the originally claimed combination of claim 10. Independent claim 27 recites a subcombination including a specified configuration of the retainer within the device that is not required by the combination of claim 10, and claim 27 has separate utility as a device for testing the level of an analyte in which liquid is retained in the specified fashion. Independent claim 30 recites a subcombination that includes a second barrel to be in fluid communication with the first barrel as recited, as well as including a chemical reactive in the second barrel, both of which are not required by the combination of claim 10. Further, claim 30 has separate utility as a device that allows flow from one barrel to a second barrel, in which a chemical is located for reaction therein. Independent claim 35 recites a subcombination that includes an adjustment member configured to move the barrier relative to the barrel such that a fixed volume of the liquid can be filled in the barrel up to the barrier, which feature is not required by the

combination of claim 10. Further, claim 35 has separate utility such as a device in which a fixed volume of liquid may be filled within the barrel by means of an adjustment member. Independent claim 40 recites a subcombination that includes a needle positioned proximate to the distal end of the barrel, which is not required by the combination of claim 10. Further, claim 40 has separate utility as a device capable of piercing an object.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

The drawings are objected to because it is unclear how the holder 5 is related to the overall syringe/pipette system shown in figure 6A-C. Figures 3A-D are hard to understand through both the brief description in the specification, and through drawings to which it is hard to see where new elements are appearing through the different embodiments. The specification references the coupling of the membrane barrier to the pipette/syringe with regards to figures 3A-C but these figures are shown in an isolated fashion where it cannot be seen how these embodiments relate to the overall pipette/syringe. Figures 6A-C show the overall system but they fail to show the previous details described which would render figures 3A-D comprehensible.

Further, the coupling device 2 is not clearly shown in the drawings for coupling the membrane to the syringe or pipette. The insert is shown, in which the specification discloses that the coupling device may be therewith connected so as to allow for altering the position of the barrier, but the coupling device is not shown in such a fashion. The coupling device 2, as shown in figures 3A-D is noted with an encompassing notation, but none of figures 3A-D show the coupling device so as to show its relation in the device, for example, so as to adapt the barrier to the testing device.

Further, with regard to figure 4, the “slidable adjustment” is not shown as disclosed in paragraph [0045] of Applicant’s pre-grant publication US 2002/0192114.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 12 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitations of claims 12 and 13 are drawn to intended use limitations of the device that do not add any further limiting structure/structural relationships to the device. The type of analyte the device is testing for does not further limit the structure of the device, and as such, any device in the prior art that contains the structural limitations of claim 10 may be used to test for the analytes listed in claims 12 and 13.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of claim 26 to the at least one reactant selected from the group as recited in claim 26, *including combinations thereof*

is not described in the specification. Applicant's specification, see paragraphs [0026-0038]+ of Applicant's pre-grant publication US 2002/0192114, discloses that there are two separate reactants used in two different reactions, and there is no support for a combination of the reactants to be used as a single reactant as recited in claim 26.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 recites "means for adjusting". The Examiner has interpreted this limitation as a means-plus-function limitation covered by 35 USC 112, sixth paragraph. This interpretation is proper since the claim limitation recites "means for" language, and the "means for" is not modified by sufficient structure for achieving the specified function. A means-plus-function limitation recites a function to be performed rather than definite structure or materials for performing that function. For claims falling under 35 USC 112, sixth paragraph, Examiners are required to construe claims as covering the corresponding structure, material, or acts described in the specification and equivalents thereof, see *In re Donaldson Co.*, 29 USPQ2d 1845 (Fed. Cir. 1994). However, the specification does not set forth the corresponding structure. Thus, it is unclear and indefinite what structure Applicant is intending to encompass with the "means for adjusting" limitation.

Examiner notes that "means for adjusting" limitation appears to come from Applicant's disclosure as the "insert secured with a holder and secured by a screw or a slidable adjustment", since the specification does support the use of such, see

paragraph [0045] of Applicant's pre-grant publication US 2002/0192114. However, clarification is required as both such possibilities contain a lack of clarity for the recited function, as will be discussed in further detail below.

Claims 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As discussed above, the specification does not provide support for the "means for" language used. Further, as discussed above the "means for adjusting" language used in claim 14 appears to correspond with the disclosure to an insert secured with a holder and secured by a screw or a slidable adjustment, since the specification does support the use of such. However, this disclosure is unclear for several reasons.

First, this disclosure is related to the variable positioning of the insert, and does not disclose the structural relationship of the variably positioned insert with respect to the barrier, so as to provide for such positioning of the barrier, operatively connected with the insert. Is the means for adjusting the position of the barrier related to the membrane that is attached to the plunger? Or is there a relationship of the insert with the barrier so as to cause the positioning of the barrier?

Further, these two examples of providing variable positioning of the insert are unclear. It is unclear how a screw provides for variably adjusting the position of the insert (as disclosed) or the barrier (as claimed). Examiner asserts that a screw appears to function as a fixing-relationship where something is maintained in a secured, static state. Further, there are no structural relationships disclosed in Applicant's specification

or claims that relate the threads of such a screw to the insert/barrier/plunger or other necessary elements so as to allow for a variable positioning of the insert/barrier/plunger relative to the threads of the screw and its relation to the necessary parts. Secondly, with regards to the disclosure of "a slidable adjustment", such disclosure is not drawn to a structural element, but is drawn to a process or act of moving. Further, Applicant's specification references figure 4 with regard to the slidable adjustment, and the figure does not show such an element. Is the "slidable adjustment" a resultant function of the combination of several structurally related elements of the pipette/syringe? Examiner asserts that as discussed above, the "means for" language of claim 14 appears to point to two possibilities, as outlined in paragraph [0045], but both possibilities have the above indefiniteness and lack of clarity in their application.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what structure allows for the insert to be adjustable to position the barrier.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The structural relationship of the screw relative to the insert is unclear so as to allow for adjusting the position of the insert. How is the screw related to insert and the barrier, so as to allow for such adjustment?

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10, 12-23, 25, and 26 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6,360,595 to Lin et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention are similar to those of the ‘595 patent, but for the additional presence of a chemical in the claims of the instant invention. The claims of the ‘595 patent are broader in all respects to those of the instant invention due to the patent’s use of “comprising” language which would allow additional components to be present. The addition of a chemical reagent as recited in the current application would have been

an obvious modification to the '595 patent so as to provide an analysis device that is ready to be used and sold with all the necessary elements included.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 12-19, 21-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro (4,750,373) in view of Moriarty (6,045,757).

Shapiro discloses an adjustable volume, pressure-generating pipette sampler (abstract; lines 5-22, col. 1). Shapiro discloses a syringe 10 with a tubular barrel 12, with a plunger (means for adjusting the position of the barrier 18) situated within the barrel, with a plunger shaft 14 (coupling device as an adjustable insert) attached to a plunger tip 18 (liquid impermeable barrier) that takes in and holds a sample (chemical reactive in the barrel between the retainer and the barrier) (line 54, col. 4 – line 22, col. 5, figs. 1&2). Shapiro further discloses screws 24, 24, and threadably fastened nuts 26, 26 to aid in mounting disc 22, which is operatively connected to the shaft 14 (insert) so as to adjust the position of the insert by how loose or tight the screws and nuts are fastened to disc 22. Shapiro further discloses that in addition, the syringe may also include a filtering attachment 50, and further that the syringe may be used to hold the samples directly within its barrel, in which case the valve 49 (retainer as a valve) is connected to the tip 20 (distal end of the barrel 12) (lines 32-67, col. 7; lines 1-67, col. 8; figs. 7&8a). Shapiro further discloses that the syringe can also be utilized for medical use by attaching a conventional syringe needle to the pipette's dispensing end 20 (lines 53-56, col. 8). With regards to claims 22 and 23, the plunger shaft 14 has radially extending flanges 14a-14d, such that the cross-section can be said to be “H” or “U” shaped (lines 18-22, col. 5). Further, Shapiro discloses that the device may be used with another syringe barrel (lines 10-13, col. 4). Additionally, Shapiro discloses that a

filtering attachment 50 or column 60 may be attached at the outlet end of the tip 47 (i.e. second barrels connectable) (lines 34-40, col. 8, figs. 8a,b).

Shapiro does not specifically disclose that the elastomeric liquid impermeable barrier is gas or vapor permeable, and comprises a hydrophobic material.

Moriarty discloses a membrane filter pipette tip such as discussed in Office Action dated 01/11/2006. Moriarty discloses that the pipette 10 is used in conjunction with a pipette tip 34. The tip 34 comprises a hollow tube having an upper/proximal end 38 and a lower/distal end 40. The upper end 38 and lower end 40 are separated by a membrane filter 32 extending across the tube, the membrane being porous to allow unrestricted passage of air, but is hydrophobic so as to discourage the passage of liquid (lines 12-21, col. 4).

It would have been obvious to modify the Shapiro device to include a gas or vapor permeable but liquid impermeable barrier of a hydrophobic material such as taught by Moriarty in order to provide a membrane barrier that prevents contamination of the area above the barrier and allowing for accurate height level of liquid being drawn in by having a liquid impermeable barrier.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro in view of Moriarty as applied to claims 10, 12-18, 21-23, and 25 above, and further in view of Yeamans (5,714,696).

Shapiro and Moriarty have been discussed above.

Shapiro discloses a second barrel in fluid communication with the first barrel, but Shapiro/Moriarty does not specifically disclose that the second barrel is in fluid communication with the first barrel by means of a second valve.

Yeamans discloses a fluid sampling apparatus in which a sampling apparatus 10 (first barrel) has an outlet valve 120, and a further connection 130,140 to a valve 170 which selectively closes off the process being sampled 180 (test manifold; i.e. second barrel) (lines 54-67, col. 4, fig. 2).

It would have been obvious to modify the Shapiro/Moriarty device so as to include a second barrel in fluid communication with the first barrel by a second valve such as taught by Yeamans in order to provide for selectively permitting/stopping fluid flow from the first barrel to the second barrel and thereby avoiding unwanted fluid flow from the first barrel to the second barrel, as well as maintaining sample in the desired amount in both barrels.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro in view of Moriarty as applied to claims 10, 12-18, 21-23, and 25 above, and further in view of Wainwright (5,171,537).

Shapiro and Moriarty have been discussed above.

Shapiro/Moriarty does not specifically disclose that the first barrel comprises at least one reactant selected from the group listed in claim 26.

Wainwright discloses an aspirator-type pipetting instrument with a removable hydrodynamically designed pipette tip, comprising a tubular body section 11(barrel), with an integral tapered nozzle section 12 with a bore 13 communicating with section

11, to which a slidable pipette tip 20 is slidably attached and the end (lines 54-58, col. 2, fig. 1&2, lines 18-31, col. 2). Wainwright additionally discloses that mounted in the bore 22 in tip 20 and lodged between axially spaced tabs 26 is a spherically shaped element 30, which is coated or impregnated with a reactive receptor substance, and is mounted for movement within the reaction chamber (lines 28-33, col. 3; lines 1-3, col. 9).

Wainwright discloses in example 1 a situation in which the coated element 30 was coated with amino silane and reacted with glutaraldehyde (lines 25-67, col. 4; lines 24-27, col. 10).

It would have been obvious to modify Shapiro/Moriarty to include an amine, such as amino silane, in the barrel so as to give the device the added functionality of being a ready-to-use device able to be used for reactions with glutaraldehyde or other relevant reactions with amino silane.

Response to Arguments

Applicant's arguments filed May 5th, 2008 have been fully considered but they are not persuasive.

With regards to the objection of the drawings, whereas all the embodiments may or may not require all of the same features, the drawings are unclear as disclosed above. The notation and markings on the drawings are unclear and in some cases, hard to understand where the elements are located, and further how the elements are arranged in the overall embodiments shown. Examiner also notes that additional drawing objections have been added above, and require Applicant's attention.

Applicant's arguments with respect to claims 10 and 12-26 have been considered but are moot in view of the new ground(s) of rejection as discussed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Application/Control Number: 10/042,904
Art Unit: 1797

Page 16

/Brian J. Sines/

Primary Examiner, Art Unit 1797